

Creating NDC Labeler Code SPL Documents

Basic instructions for creating
technically valid NDC Labeler Code
SPL Documents

Version 1.0

Use SPL Starter Package

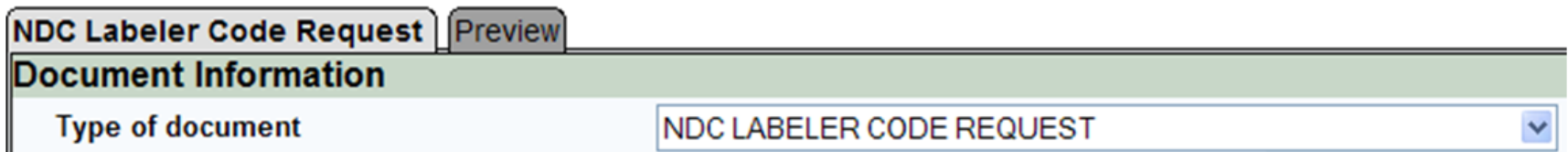
- Link to SPL Starter Package is located under the heading "Resources" on this web page:

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

Accessing the NDC LCR SPL Xforms

- Open NDC Labeler Code SPL document Xforms file “SPLForm_LabelerCode.xhtml” (or equivalent in your SPL authoring software.)
- Use the NDC Labeler Code SPL document to submit already assigned NDC labeler codes or to request new labeler codes.

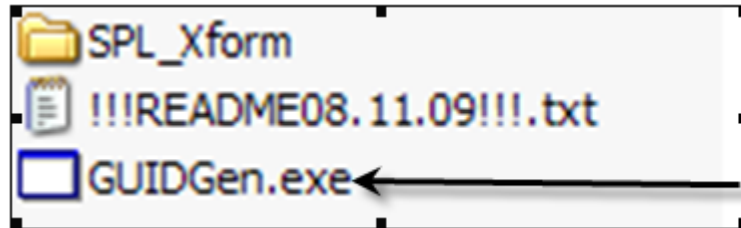
Selecting Document Type



The screenshot shows a web form with two tabs: 'NDC Labeler Code Request' and 'Preview'. The 'NDC Labeler Code Request' tab is active. Below the tabs is a section titled 'Document Information'. Within this section, there is a label 'Type of document' followed by a drop-down menu. The drop-down menu is open, showing the selected option 'NDC LABELER CODE REQUEST'.

- Select “NDC Labeler Code Request” from the drop-down menu.

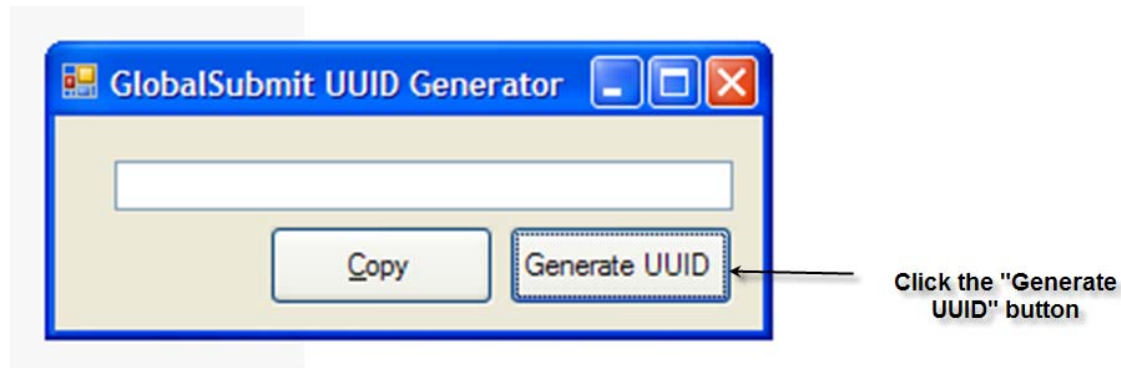
Generating GUIDs for IDs



Use the **GUID** generator executable file
or online version

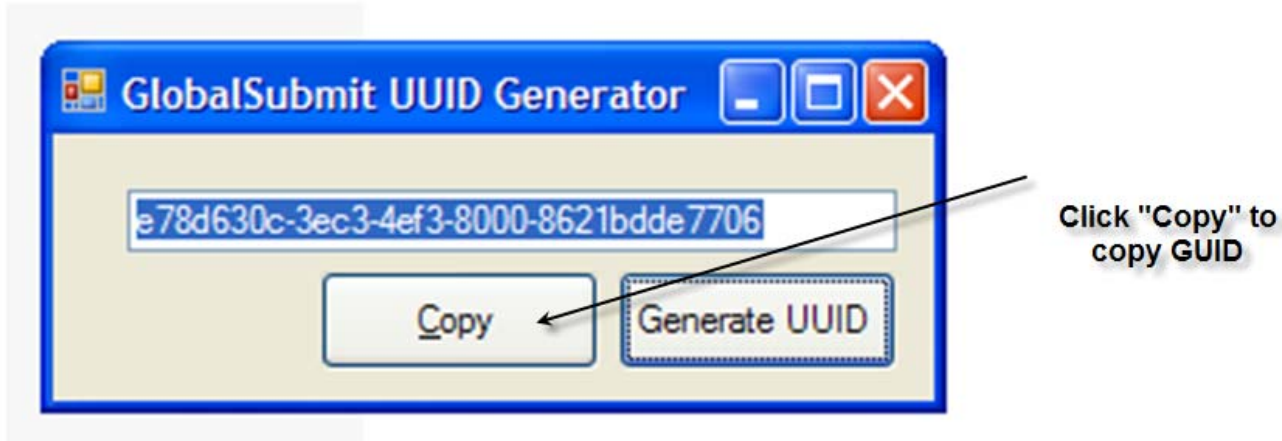
- Locate the Globally Unique Identifier (GUID) generator in the folder containing the SPL Xforms. GUIDs are also referred to as Universal Unique Identifiers (UUIDs)
- Double click executable file named “GUIDGen.exe.”
- If this program is incompatible with your PC, then search for an “online GUID generator” via your internet browser.

Generating GUIDs for IDs cont...



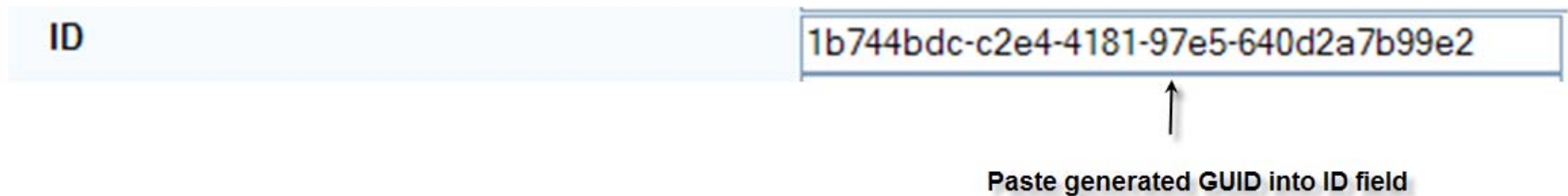
- Generate a GUID by choosing the “Generate UUID” button (or equivalent in online GUID generator tool.)

Generating GUIDs for IDs cont...



- Copy a GUID by choosing the “Copy” button (or equivalent in online GUID generator tool.)

Adding a SPL Document ID



- Paste GUID in “ID” field
- The id root uniquely identifies a specific SPL file. Each new version of an SPL file has a new id root. The id root is a Globally Unique Identifier (GUID).
- Hereafter, the “id root” will be referred to as “ID” in this eBook.

Assigning a Set ID

Set ID

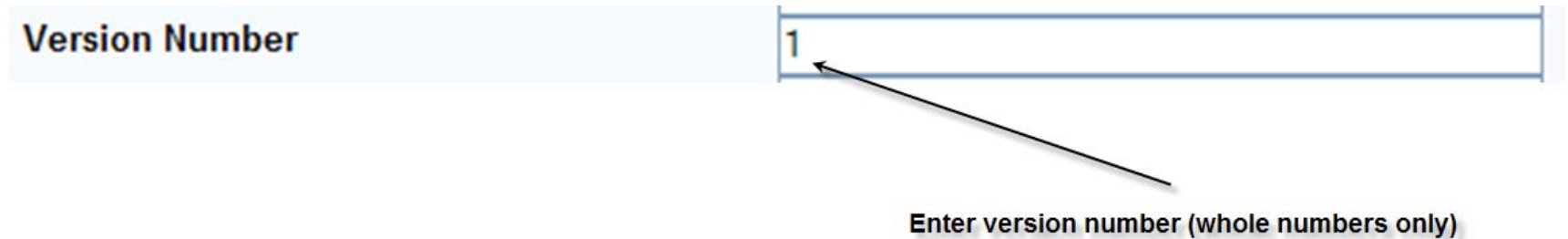
b81824ab-c543-426c-bb45-7e6ab4e253c0



Generate another GUID and paste in the setID field

- Generate and copy another GUID using the GUID generator.
- Paste this GUID in the “Set ID” field.
- The setID root uniquely identifies a group of versions of an SPL file.

Version Number



A form with a light blue header bar containing the text "Version Number". To the right of the header is a white input field with a blue border. The number "1" is entered in the input field. An arrow points from the text "Enter version number (whole numbers only)" below to the input field.

Version Number

1

Enter version number (whole numbers only)

- Enter a version number.
- The version number must be a whole number greater than zero.
- No spaces should be included before or after the version number.

Entering a Document Date

Effective Time

20090920

Enter approximate submission date

- Enter a document date (Effective Time)
- Ensure that there are no spaces (created w/space bar) before or after date.
- The effective time provides a date reference to the SPL version. The date includes the year, month and day using the format `yyyymmdd`.

Entering the Labeler's Name

Labeler	
Name	<input type="text" value="Acme Inc."/>

Enter name of owner of labeler code

- Type in the name of the labeler.
- The labeler is the registrant or private label distributor (PLD) requesting the NDC Labeler Code or the registrant or PLD who is submitting an already assigned NDC Labeler Code.

Labeler's DUNS Number

Labeler	
Name	Acme Inc.
DUNS Number	528352112

↑
Enter DUNS Number for labeler

- Type the DUNS Number for the labeler code owner's headquarters.
- Ensure no hyphens are included in the DUNS Number.
- Do not include spaces (created w/space bar) before or after DUNS Number

Adding a NDC Labeler Code

The screenshot shows a web form titled 'Labeler'. It has two input fields: 'Name' with the value 'Acme Inc.' and 'DUNS Number' with the value '528352112'. Below these fields are two buttons: 'Add NDC Labeler Code' and 'Delete NDC Labeler Code'. Two arrows point from the text below to these buttons. The first arrow points to the 'Add NDC Labeler Code' button and is accompanied by the text: 'If no labeler code is assigned, DO NOT click "Add NDC Labeler Code" button'. The second arrow points to the 'Delete NDC Labeler Code' button and is accompanied by the text: 'If you accidentally add field, use the "Delete NDC Labeler Code" button to remove field'.

Labeler	
Name	Acme Inc.
DUNS Number	528352112
<input type="button" value="Add NDC Labeler Code"/> <input type="button" value="Delete NDC Labeler Code"/>	

If no labeler code is assigned, DO NOT click "Add NDC Labeler Code" button

If you accidentally add field, use the "Delete NDC Labeler Code" button to remove field

- If **requesting** a labeler code, **DO NOT** select the "Add NDC Labeler Code" button.
- If you accidentally select button, then choose "Delete NDC Labeler Code" button.

Entering an NDC Labeler Code

The screenshot shows a form titled "Labeler" with a light green header. Below the header are three input fields: "Name" with the value "Acme Inc.", "DUNS Number" with the value "528352112", and "NDC Labeler Code" with the value "35521". Below these fields are two buttons: "Add NDC Labeler Code" and "Delete NDC Labeler Code". An arrow points from the "Add NDC Labeler Code" button to the text "If a labeler code has been assigned, click 'Add NDC Labeler Code' button". Another arrow points from the "Delete NDC Labeler Code" button to the text "Populate field with NDC Labeler Code".

Labeler	
Name	Acme Inc.
DUNS Number	528352112
NDC Labeler Code	35521
<input type="button" value="Add NDC Labeler Code"/> <input type="button" value="Delete NDC Labeler Code"/>	

If a labeler code has been assigned, click "Add NDC Labeler Code" button

Populate field with NDC Labeler Code

- If labeler code is **already assigned**, select “Add Labeler Code” button and enter 4-5 digit NDC Labeler Code that is completely identical to the NDC Labeler Code that is the first segment of your 3-segment 10-digit NDC.

Contact Person's Name



The image shows a screenshot of a web form. At the top, there is a green header bar with the word "Contact" in white. Below this is a light blue section containing a label "Name" on the left and a text input field on the right. The input field contains the text "Deborah Tyler". Below the input field, there is a black arrow pointing upwards towards the field, and the text "Enter contact person's name" is written below the arrow.

- The contact is the person FDA contacts regarding the NDC Labeler Code request.
- Enter the contact person's name in the name field.

Contact Person's Address

Mailing Address

352 Turner Avenue

- Enter the street and number of the mailing address for the contact person.

Enter City

City	Rockville
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- Enter the city for the mailing address for the contact person

Enter State or Province

State

MD

- Enter the state for the mailing address for the contact person. (Use state abbreviation)
- If there is no state, as with certain addresses outside the United States, leave the field empty.
- Provinces can be entered in the state field.

Entering Country Code

Country

USA

- Enter the **three-character** character country code using the ISO 3166-1 standard for the mailing address for the contact person.
- Do not include spaces (created w/space bar) before or after country code.
- Link to country code lists:
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162567.htm>

Postal Codes

Postal Code	20857
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- Enter the postal code for the mailing address for the contact person.
- If there is no postal code, as with certain addresses outside the United States, leave the field empty.

Telephone Number

Telephone Number

tel:+1-888-232-5532

- Enter the contact telephone number for the contact person.
- Ensure that there are no spaces (created w/space bar) before or after telephone number.
- Telephone numbers are global telephone numbers using the Uniform Resource Identifier (URI) for Telephone Numbers RFC 3966 (no letters; begin with “+”; **include hyphens to separate the country code, area codes and subscriber number**; extensions are separated by “;ext=”).

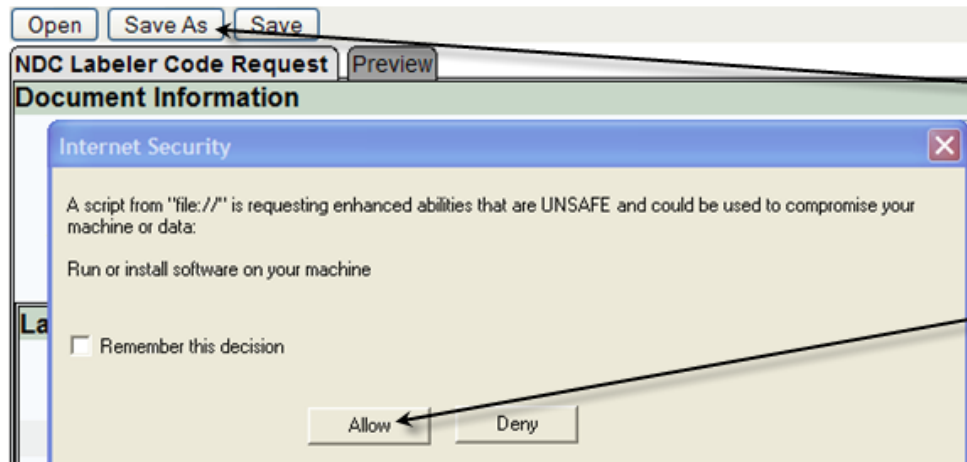
E-mail address

Email Address

mailto:deborah.tyler@acme.com

- Enter the email address for the contact person.
- Ensure that there are no spaces (created w/space bar) before or after e-mail address.

Saving the File

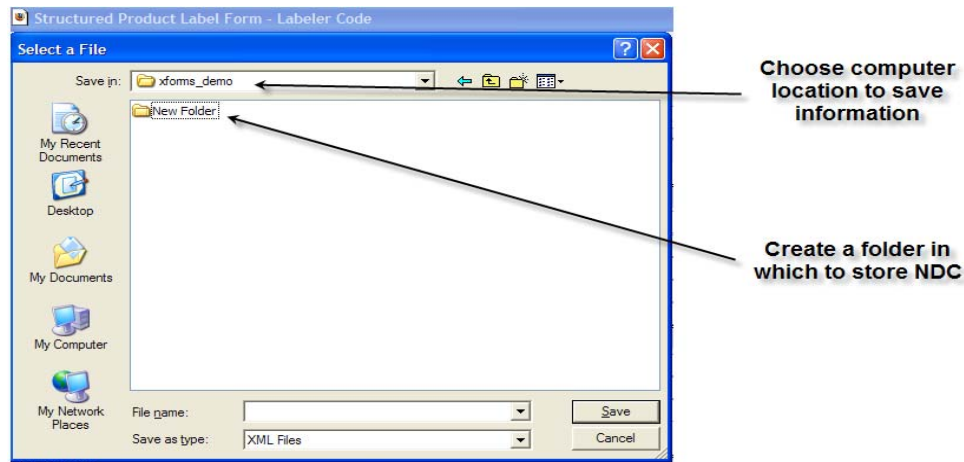


Choose "Save As" button to save file.

Then click "Allow" button to acknowledge security note.

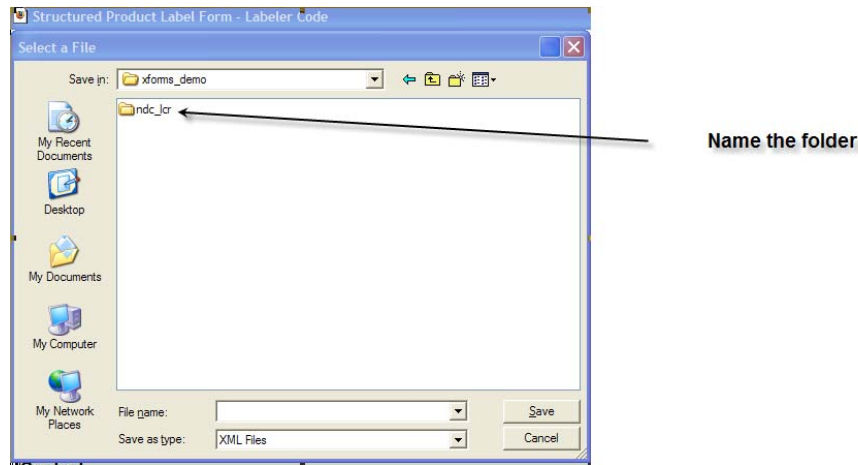
- When saving the SPL file for the first time, select the “Save As” button.
- Then select the “Allow” button to continue saving.
- You can check “Remember This Decision” checkbox to avoid future security prompts.

Creating the Submission Folder



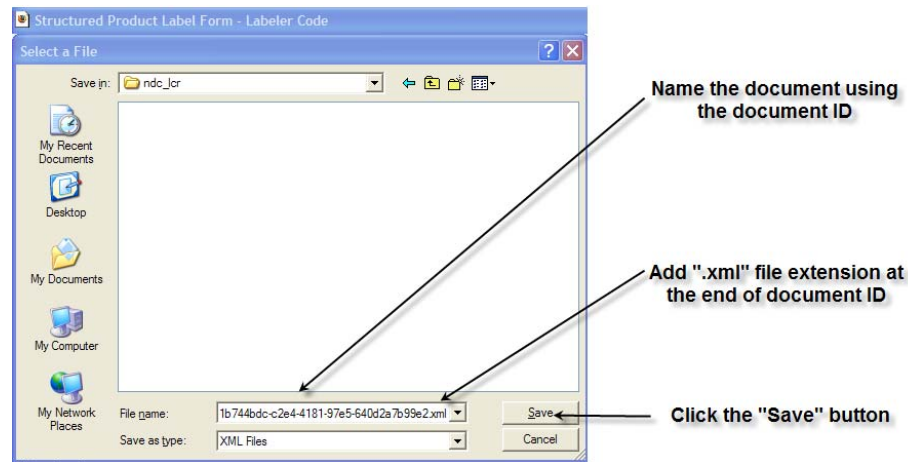
- Choose computer location in which to store folder to contain the SPL file.
- Create a folder in which to store the NDC Labeler Code SPL file.

Naming the Submission Folder



- There is no folder naming convention
- However, we recommend not using symbols in the name of the folder.

Naming the SPL File



- Use the **document ID** (GUID) as the document file name
- Use “.xml” as the file extension
- Choose “Save” button
- If you do not follow these steps your SPL will **FAIL** validation.

Review NDC LCR SPL Document

Acme Inc.

Product Information	
Product Type	NDC LABELER CODE REQUEST

Labeler - Acme Inc. (528352112) NDC Labeler Code: 35521			
Contact	Address	Telephone Number	Email Address
Deborah Tyler	Address: 352 Turner Avenue City, State, Zip: Rockville, MD, 20857 Country: USA	+1-888-232-5532	deborah.tyler@acme.com

Revised: 09/2009

Acme Inc.

- Navigate to computer location and double click the SPL file icon to open file.
- If you can not view the file, then neither can FDA.
- Send File to FDA via FDA “OC” Gateway

Need More Detailed Instructions?

- Use Step-by-Step Instructions for Creating Structured Product Labeling (SPL) Files for Drug Establishment Registration and Drug Listing
- This document is located on the SPL Resources web page:
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

Test Your SPL R4 Submissions

- Use Pragmatic Data Validator Lite to test your SPL files prior to transmission to FDA:
<http://www.fda.gov/ForIndustry/DataStandards/ucm155514.htm>
- **IMPORTANT** – Ignore the error regarding the missing labeler code which will result from testing NDC Labeler Codes that are actual requests for new labeler codes.
- Fix all other errors before submitting to FDA.

Submitting Files via FDA Gateway

WebTrader Help Logout

Send document

Select who will receive the document

Gateway: FDATST

Center: **Select the "OC" center**

Select the contents of the submission

Enter a path to a file or a directory. If a directory is entered, then the entire contents of the directory will be included in the submission. All the paths stored in the submission will be relative from the provided directory path unless an alternate root directory is entered.

Path: **Browse...** **Ensure that you are submitting SPL in a folder (file name should not appear in the path field)**

Root directory: **Browse...**

Submission type: **Select "SPL" as the submission type**

Select a signing certificate

Current file: M:\SPL_Main\gateway\Lonnie Smith\Lonnie Smith.p12

New file: **Browse...**
MyCertificate.p12 or MyPrivateKey.pfx

Send

Stay Informed

- Join FDA Data Standards Council listserv
- <http://www.fda.gov/ForIndustry/DataStandards/default.htm>



The screenshot shows the FDA Data Standards Council website. At the top is the U.S. Department of Health & Human Services header with the www.hhs.gov link. Below is the FDA U.S. Food and Drug Administration logo and a search bar. A navigation bar lists various FDA categories. The 'For Industry' section is highlighted, with a breadcrumb trail: Home > For Industry > Data Standards. On the left is a 'Data Standards' sidebar menu with links to Validators, Data Council, Structured Product Labeling, Individual Case Safety Reports, and Regulated Product Submission. The main content area is titled 'FDA Resources for Standards' and features a 'Sign up for email updates.' link with an arrow pointing to it. Below this is a paragraph about the council's role and a link to 'Structured Product Labeling'.

U.S. Department of Health & Human Services www.hhs.gov

FDA U.S. Food and Drug Administration

A-Z Index Search go

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

For Industry Email this page Print this page Change Font Size

Home > For Industry > Data Standards

Data Standards

- Validators
- Data Council
- Structured Product Labeling
- Individual Case Safety Reports
- Regulated Product Submission

FDA Resources for Standards

 Sign up for email updates. ←

The FDA Data Standards Council coordinates the evaluation, development, maintenance, and adoption of health and regulatory data standards to ensure that common data standards are used throughout the agency.

[Structured Product Labeling](#)

SPL-related Technical Assistance/Questions

- SPL e-mail account (spl@fda.hhs.gov)